REMARKS

In response to the Non Final Office Action dated April 7, 2008, no claims have been amended, added, or canceled. Claims 1-18 and 25-28 are currently under examination. Favorable reconsideration of the subject application is respectfully requested in view of the following remarks.

Summary of Examiner Interview

The telephonic interview on July 29, 2008 was conducted and attended by Examiner Karen Canella and Dr. William Christiansen (Reg. No. 44,614). During the interview, Applicant's representative discussed written description support for fluence units as recited in the instant claims (e.g., between 500 joules/cm^2 and 10,000 joules/cm^2). It was pointed out to the Examiner that support for the fluence units recited in the instant claims can be found in originally filed claim 21. Neither exhibits nor demonstrations were used during the interview.

Claims Rejection Under 35 U.S.C. §112, First Paragraph, Written Description

Claims 1-18 and 25-28 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Examiner alleges that the claims contain subject matter which was not described in such a way as to reasonably convey to the skilled artisan that the Applicant was in possession of the claimed invention at the time of filing the instant application.

Applicant respectfully traverses this basis for rejection and submits that the as-filed specification provides full written description support for the entire breadth of the presently claimed invention. Furthermore, one having ordinary skill in the art would reasonably conclude that Applicant was in possession of the presently claimed invention at the time of filing the instant application.

The Examiner alleges that the limitation "between 500 joules/cm^2 and 10,000 joules/cm^2" recited in claims 1 and 2 is not supported by the originally filed disclosure. Applicant respectively submits that original claim 21 recited: "The method of claim 1 or 2, wherein the total fluence of the light used for irradiating is between 500 Joules/cm^2 and 10,000

Joules/cm^2." Applicant submits that an original claim may provide written description support for a claim limitation. "An original claim may provide adequate written description of the claimed invention. It is equally a written description whether located among the original claims or in the descriptive part of the specification." *Application of Gardner, 480 F.2d 879, 178 U.S.P.Q. 149 (C.C.P.A. 1973).* Thus, one having ordinary skill in the art would recognize Applicant to be in possession of the presently claimed units of fluence.

Furthermore, the specification on page 15, line 3, lines 8-9, and line 12 describes an embodiment of the presently claimed invention that uses a light source having an intensity between 5 and 100 mW/cm^2, a duration of radiation exposure between about 2 hours and 24 hours, and a total number of joules delivered to the treatment site of between 500 J to 10,000 J. The only unit area described for fluence in the as-filed specification are square centimeters; thus, one having ordinary skill in the art would reasonable conclude that the total fluence of light is delivered to a unit area per square centimeter (*e.g.*, original claim 21) administered over a time period of about 2 to 24 hours using a light source having an intensity of between about 5 and $100mW/cm^2$. Moreover, the skilled artisan may calculate the relationships of light intensity, duration of irradiation, and total fluence delivered to a treatment area using the parameters found in the as-filed specification. By way of non-limiting example, Applicant submits that a light source having an intensity of $70mW(.07J/sec)/cm^2$, administered for a duration of 2 hours (7200 seconds), would produce a total fluence of about 500 J/cm^2. Likewise, the same light source, administered for a duration of 24 hours (86400 seconds), would produce a total fluence of about 6000 J/cm^2. In a further example, a light source having an intensity of $100mW(.1J/sec)/cm^2$, administered for a duration of 2 hours (7200 seconds), would produce a total fluence of about 720 J/cm^2. Likewise, the same light source, administered for a duration of 24 hours (86400 seconds), would produce a total fluence of about 8640 J/cm^2. Thus, the skilled artisan would reasonable conclude that the as-filed specification supports embodiments of the presently claimed combinations of light source intensity, duration of irradiation, and total fluence delivered to a treatment area.

Accordingly, Applicant submits that the presently claimed invention more than adequately satisfies the written description requirements under 35 U.S.C. §112 and request reconsideration of this rejection.

Claims Rejection Under 35 U.S.C. §112, First Paragraph, Enablement

Claims 1-18 and 25-28 stand rejected under 35 U.S.C. §112, first paragraph, because the specification allegedly fails to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Specifically, the Examiner alleges that while the specification enables ligands which are antibodies that specifically bind target lesion specific antigen; the specification allegedly fails to reasonably provide enablement for ligands which are part of a ligand-receptor bind pair such as biotin-streptavidin, chemokine-chemokine receptor, growth factor-growth factor receptor, or ligands which are LDL, VLDL, heparin or angiotensin II.

Applicant respectfully traverses this basis for rejection and submits that the as-filed specification fully enables the presently claimed invention. Moreover, Applicant submits that the skilled artisan would not be subjected to undue experimentation in order to practice the entire breadth of presently claimed invention.

The Examiner rightly contends that it is well known in the art that antibodies can be used to specifically target diagnostic or therapeutic agents *in vivo* to specific site via antigen-antibody interactions which are specific to the targeted tissues. However, the Examiner further contends that there are no teachings in the specification or art of record which support the use of a targeting agent to a vascular lesion which was based on the specific binding of biotin/streptavidin, a chemokine, a growth factor, LDL, VLDL, heparin, or angiotension II to vascular lesions.

With regard to claim 1, Applicant respectfully points out that the as-filed specification teaches that Heparin®, Angiotensin II®, LDL, and VLDL are all localized to various vascular lesions, and thus, would serve to localize a photosensitizing agent to a particular lesion (see as-filed specification page 18, lines 13-23). Applicant submits that Heparin® and

Angiotensin II® have been used in the art to treat lesions of the vascular system, and that LDL and VLDL are well known to be associated with arterial plaques and/or vascular lesions.

Moreover, as recognized by the Examiner, the skilled artisan is experienced and knowledgeable regarding antibodies that target specific antigens, and thus, must also be familiar with and know the identity of said target lesion specific antigens. Applicant submits that using an antibody that recognizes a target lesion specific antigen (e.g., a receptor) would be considered similar to using a ligand that recognizes the same target lesion specific antigen (i.e., the receptor). Applicant submits that it would be well within the ordinary skill of one in the art to select the appropriate agent or ligand that recognizes a vascular lesion. Such would constitute merely routine, not undue, experimentation.

Applicant respectfully points out that instant claim 2 recites "a first member of a ligand-receptor binding pair conjugated to **an antibody or antibody fragment**, wherein the antibody or antibody fragment selectively binds to the target cell that comprises the lesion in the arterial vascular system." As mentioned above, the Examiner has acknowledged that such antibodies are well-known in the art. Applicant respectfully submits that it is also well-known in the art that avidin and streptavidin do not exist in humans; thus, a first member of a ligand-receptor binding pair comprising an antibody to a target lesion specific antigen conjugated to biotin or avidin/streptavidin would be specifically recognized by a second member comprising the photosensitizing agent conjugated to avidin/streptavidin or biotin, respectively.

Moreover, as the first member of the ligand-receptor binding pair comprises an antibody to a target lesion specific antigen conjugated to the ligand, any ligand-receptor binding pair may be used in the presently claimed invention provided the ligand-receptor binding pair demonstrates a specificity for the binding of the ligand to the receptor (e.g., biotin/streptavidin, see as-filed specification on page 17, lines 1-2). It would be well within the skilled artisan's ability to choose such a suitable ligand-receptor binding pair. One having ordinary skill in the art would clearly understand that a first member comprising an antibody specific to a target lesion antigen provides tissue specificity for the photosensitizing agent.

Accordingly, in view of the instant disclosure, Applicant submits that the as-filed specification fully enables one of ordinary skill in the art to practice the presently claimed

invention without undue experimentation. Reconsideration and withdrawal of this basis of rejection is respectfully requested.

Applicant respectfully submits that claim 25 depends from claim 1 and recites a limitation of using an antibody specific to a target antigen; thus, claim 25 was improperly rejected under the present basis of rejection, and is believed to be allowable. In addition, Applicant respectfully submits that all of the claims remaining in the application are now believed to be in condition for allowance. Favorable consideration and a Notice of Allowance are earnestly solicited.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Respectfully submitted,

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